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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/590,780	10/10/2006	Janez Kerc	029489-00023	1166

4372 7590 07/29/2009

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EXAMINER
ARNOLD, ERNST V

ART UNIT	PAPER NUMBER
1616	

NOTIFICATION DATE	DELIVERY MODE
07/29/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/590,780	KERC ET AL.	
	Examiner	Art Unit	
	ERNST V. ARNOLD	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 May 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) *1-12,15 and 16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13,14 and 17-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *25 August 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/4/09; 8/25/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's election without traverse of Group II, claims 13 and 14 in the reply filed on 5/4/09 is acknowledged. Claims 1-12, 15 and 16 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected subject matter, there being no allowable generic or linking claim. Applicant has added new claims 17-21 to group II. Accordingly claims 13, 14, and 17-21 are presented for examination.

Comment: In claim 21, "prevastatin" appears to be a misspelling of pravastatin. Please correct.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Specification

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The following title is suggested: Stabilized Pravastatin Polymorph Compositions.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 21 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 21 introduces new matter as the claim recites the limitation: "the ratio of prevastatin sodium to microcrystalline cellulose is greater than 2" There is no support in the specification for this limitation. The limitation of: " the ratio of prevastatin sodium to microcrystalline cellulose is greater than 2" was not described in the specification as filed, and person skilled in the art would not recognize in the applicant's disclosure a description of the invention as presently claimed. The specification discloses "the weight ratio of prevastatin sodium to microcrystalline cellulose is above 1.0" in original claim 7 but does not describe the instantly claimed limitation. There is no guidance in the specification to select "the ratio of prevastatin sodium to microcrystalline cellulose is greater than 2" and from MPEP 2163.06: "Applicant should therefore specifically point out the support for any amendments made to the disclosure." Applicant has not directed the Examiner to the support in the specification for the amendments. Therefore, it is the Examiner's position

that the disclosure does not reasonably convey that the inventor had possession of the subject matter of the amendment at the time of filing of the instant application.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 14 and 17-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 14 and 17 recite: “significant peaks”. It is unclear what a significant peak is because significant is a relative term and it is unknown what is insignificant. In other words, significant to what? Claims 18-21 are rejected as being indefinite because they are dependent on an indefinite base claim. The claims will be examined as they read upon any X-ray diffraction pattern peaks.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 21 recites the limitation "prevastatin sodium" in line 2. There is insufficient antecedent basis for this limitation in the claim. Claim 13 does not recite prevastatin sodium.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 13 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Dempski et al. (US 4173626).

Dempski et al. disclose in claim 3:

> 3. The pharmaceutical formulation of claim 1, wherein component (A) is pellets comprising 10–35% by weight indomethacin; 20–40% by weight confectioner's sugar; 3–15% by weight of hydroxypropylmethylcellulose; 3–15% by weight corn starch; and 15–25% by weight microcrystalline cellulose; and component (B) is component (A) pellets coated with said slow dissolving material.
>
> * * * * *

Dempski et al. teach a capsule in claim 1. Therefore, when 35% indomethacin, a pharmaceutical ingredient, is present and 15% microcrystalline cellulose is present a weight ration of active to microcrystalline cellulose of greater than 1 is achieved. Please note that claim 13 reads on a product by process. With respect to the USC 102 rejection above, please note that in product-by-process claims, once a product appearing to be substantially identical is found and a 35 U.S.C. 102 rejection [is] made, the burden shifts to the applicant to show a difference. MPEP 2113. This rejection under 35 U.S.C. 102 is proper because the "patentability of a product does not depend on its method of production." *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 13, 14, and 17-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pflaum (US 6740775) in view of Kofler et al. (US 6511972).

Applicant claims a pharmaceutical compositions and a stabilized pharmaceutical composition.

Determination of the scope and content of the prior art

(MPEP 2141.01)

Pflaum teaches pharmaceutical compositions of the sodium salt of pravastatin in a crystalline form and methods of making them (claims 1-19). The X-ray diffraction pattern in Figure 2; shown below:

Figure 2

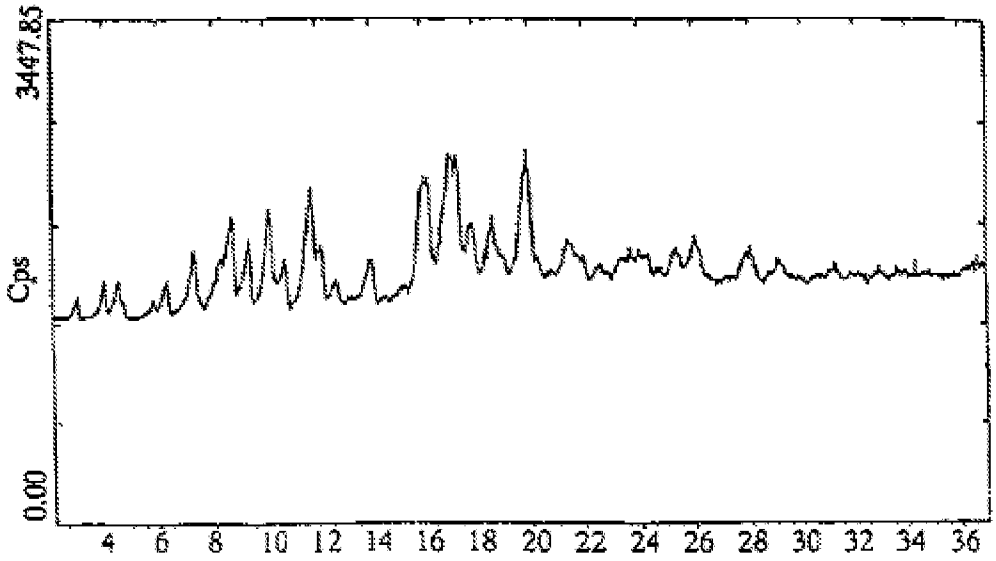

FIG. 2 is a diffractogram of crystals of the sodium salt of pravastatin prepared according to Example 2 of the present invention, which are scanned on the X-ray powder diffractometer within 2 to 48° 2Θ range with a 0.035° 2Θ step and an integration time of 1 second/step.

Applicant teaches that the instantly claimed process produces crystalline pravastatin sodium substantially similar to figure 2 above (original claim 9) and thus has the essentially same X-ray diffraction pattern with significant peaks and half value widths which equates the prior art product with that which is instantly claimed.

Tablets are taught (column 5, lines 23-25 and column 6, lines 3-9). Microcrystalline cellulose is taught as a filler (column 5, lines 27-29).

Pflaum teaches methods of making the pravastatin in the presence of ethanol or methonal in column 4, lines 26-52 reproduced below:

> The process for the preparation of crystals according to the present invention as described above comprises the following steps:
>
> (a) Providing a solution containing pravastatin and sodium cations in a lower aliphatic alcohol. This is suitably carried out by dissolution of an solid and/or amorphous sodium salt of pravastatin in a lower aliphatic alcohol having preferably 1 to 4 carbon atoms. More preferably, the alcohol used for the dissolution of pravastatin sodium is ethanol or methanol. The best crystallization results have been achieved when preparing a solution of pravastatin sodium in methanol.
>
> (b) Adding ethyl acetate into the alcoholic solution, preferably while the alcoholic solution obtained in step (a) is stirred continually. The addition of ethyl acetate into the alcoholic solution of pravastatin sodium is preferably carried out slowly, while the addition may be continuously or stepwise.
>
> (c) Cooling the resulting alcohol/ethyl acetate mixture; and
>
> (d) Crystallizing the sodium salt of pravastatin.
>
> In step (d) from the cooled mixture crystals of the sodium salt of pravastatin, which preferably have a colorless or pale yellow appearance and are in the form of needles or radiating clusters, are formed.
>
> Additionally, the crystals obtained by this process may preferably be filtered, ethyl acetate washed and dried.

Pflaum teaches a process of preparing the sodium salt of pravastatin using open language (claim 6).

Kofler et al. teach microcrystalline cellulose such as Avicel PH 112 having a particle size from 20 to 100 microns for capsule and tablet formulations (column 2, lines 10-15).

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

1. The difference between the instant application and Pflaum is that Pflaum do not expressly teach adding microcrystalline cellulose that has an average particle size of from 10 to 200 microns and a weight ratio of pravastatin to microcrystalline cellulose of greater than 1. This deficiency in Pflaum is cured by the teachings of Kofler et al.

Finding of prima facie obviousness

Rational and Motivation (MPEP 2142-2143)

1. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to add microcrystalline cellulose that has an average particle size of from 10 to 200 microns and a weight ratio of pravastatin to microcrystalline cellulose of greater than 1, as suggested by Kofler et al., to the composition of Pflaum and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because: 1) Pflaum teaches adding microcrystalline cellulose to the formulation but simply does not name a brand or particle size and the art of Kofler et al. teaches commercially available sources of microcrystalline cellulose within the particle size claimed and 2) the instant claims read on a product by process. Please note that in product-by-process claims, once a product appearing to be substantially identical is found and a 35 U.S.C. 103 rejection [is] made, the burden shifts to the applicant to show an obvious difference. MPEP 2113. This rejection under 35 U.S.C. 103 is proper because the “patentability of

a product does not depend on its method of production." *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985).

. With regards to the weight ratio, it is the position of the Examiner that this is merely a matter of routine optimization. The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient needed to achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, the optimization of ingredient amounts would have been obvious at the time of applicant's invention. The composition would be intrinsically stabilized against converting into one exhibiting peaks having half value widths of significant peaks above 2 degree 2 Theta in the absence of evidence to the contrary.

With regard to the "wet phase" limitation, the stabilized composition is stabilized in wet or dry phase because such stabilization is intrinsic no matter the phase.

In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of

ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 13, 14, and 17-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Keri et al. (WO 01/43723) in view of Kofler et al. (US 6511972).

Applicant claims a pharmaceutical compositions and a stabilized pharmaceutical composition.

Determination of the scope and content of the prior art

(MPEP 2141.01)

Keri et al. teach novel forms of pravastatin sodium, methods of making and methods of using the pravastatin sodium (Abstract and claims 1-203). Tablets are disclosed and may contain diluents such as microcrystalline cellulose (page 13, lines 4-7). Capsules are also taught (page 13, lines 24-27). With regard to the significant peaks having half-value widths below 2 degrees 2 theta, the U.S. Patent Office is not equipped with analytical instruments to test prior art compositions for the infinite number of ways that a subsequent applicant may present previously unmeasured characteristics. When as here, the prior art appears to contain the exact same ingredients and applicant's own disclosure supports the suitability of the prior art composition as the inventive composition component, the burden is properly shifted to applicant to show otherwise.

Kofler et al. teach microcrystalline cellulose such as Avicel PH 112 having a particle size from 20 to 100 microns for capsule and tablet formulations (column 2, lines 10-15).

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

1. The difference between the instant application and Keri is that Keri do not expressly teach adding microcrystalline cellulose that has an average particle size of from 10 to 200 microns and a weight ratio of pravastatin to microcrystalline cellulose of greater than 1. This deficiency in Keri is cured by the teachings of Kofler et al.

Finding of prima facie obviousness

Rational and Motivation (MPEP 2142-2143)

1. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to add microcrystalline cellulose that has an average particle size of from 10 to 200 microns and a weight ratio of pravastatin to microcrystalline cellulose of greater than 1, as suggested by Kofler et al., to the composition of Keri and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because: 1) Keri teaches adding microcrystalline cellulose to the formulation but simply does not name a brand or particle size and the art of Kofler et al. teaches commercially available sources of microcrystalline cellulose within the particle size claimed and 2) the instant claims read on a product by process. Please note that in product-by-process claims, once a product appearing to be substantially identical is found and a 35 U.S.C. 103 rejection [is] made, the burden shifts to the applicant to show an obvious difference. MPEP 2113. This rejection under 35 U.S.C. 103 is proper because the "patentability of a product does not depend on its method of production." *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985).

With regards to the weight ratio, it is the position of the Examiner that this is merely a matter of routine optimization. The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each

ingredient needed to achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, the optimization of ingredient amounts would have been obvious at the time of applicant's invention. The composition would be intrinsically stabilized against converting into one exhibiting peaks having half value widths of significant peaks above 2 degree 2 Theta in the absence of evidence to the contrary.

With regard to the "wet phase" limitation, the stabilized composition is stabilized in wet or dry phase because such stabilization is intrinsic no matter the phase.

In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140

F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

1. Claims 13, 14, and 17-21 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 7, 14, 17, 18, 19, 25, 32, 33, and 39 of U.S. Patent No. 6680341 in view of Pflaum (US 6740775) and Kofler et al. (US 6511972). The references of Pflaum and Kofler et al. are discussed in detail above and those discussions are hereby incorporated by reference. The instant subject matter embraces or is embraced by the copending subject matter. US 6680341 teaches stable/stabilized pharmaceutical formulations of sodium pravastatin and fillers. The disclosure encompasses all polymorphs of sodium pravastatin.

US 6680341 does not expressly teach the filler to be microcrystalline cellulose of a particular particle size and ratio with the active.

However, the art teaches using microcrystalline cellulose in sodium pravastatin formulations and the art teaches microcrystalline cellulose within the instant particle size. It would be obvious to use microcrystalline cellulose in the stable/stablized pravastatin formulations taught in 6680341 because the art suggests doing so. With regards to the weight ratio of ingredients; the amount of a specific ingredient in a

composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient needed to achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, the optimization of ingredient amounts would have been obvious at the time of applicant's invention. Please note that in product-by-process claims, once a product appearing to be substantially identical is found and a 35 U.S.C. 103 rejection [is] made, the burden shifts to the applicant to show an obvious difference. MPEP 2113. This rejection under 35 U.S.C. 103 is proper because the "patentability of a product does not depend on its method of production." *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985).

Thus, one of ordinary skill in the art would have recognized the obvious variation of the instant invention over the patent in view of the cited references.

2. Claims 13, 14, and 17-21 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 12, 13, and 17 of U.S. Patent No. 6531507 in view of Pflaum (US 6740775) and Kofler et al. (US 6511972). The references of Pflaum and Kofler et al. are discussed in detail above and those discussions are hereby incorporated by reference. The instant subject matter embraces or is embraced by the copending subject matter. US 6531507 teaches pharmaceutical formulations of sodium pravastatin and fillers. The disclosure encompasses all polymorphs of sodium pravastatin.

US 6531507 does not expressly teach the filler to be microcrystalline cellulose of a particular particle size and ratio with the active.

However, the art teaches using microcrystalline cellulose in sodium pravastatin formulations and the art teaches microcrystalline cellulose within the instant particle size. It would be obvious to use microcrystalline cellulose in the pravastatin formulations taught in US 6531507 because the art suggests doing so. With regards to the weight ratio of ingredients; the amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient needed to achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, the optimization of ingredient amounts would have been obvious at the time of applicant's invention. Please note that in product-by-process claims, once a product appearing to be substantially identical is found and a 35 U.S.C. 103 rejection [is] made, the burden shifts to the applicant to show an obvious difference. MPEP 2113. This rejection under 35 U.S.C. 103 is proper because the "patentability of a product does not depend on its method of production." *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985).

Thus, one of ordinary skill in the art would have recognized the obvious variation of the instant invention over the patent in view of the cited references.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ernst V. Arnold whose telephone number is 571-272-8509. The examiner can normally be reached on M-F (7:15 am-4:45 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Ernst V Arnold/
Examiner, Art Unit 1616